

The objection to claim 11

Applicants respectfully submit that cancellation of claim 11 renders the objection moot.

The 35 U.S.C. § 101 Rejections of the Claims

The Examiner rejected claims 1-37 under 35 U.S.C. § 101 alleging that the claimed invention lacks patentable utility due to its not being supported by either a specific and/or substantial utility or a well-established utility. Applicants respectfully submit that cancellation of claims 1-37 and addition of new claims 38-88 overcome the Examiner's rejections.

Applicant respectfully submits that the claimed invention has specific and substantial utilities. New claims 38-88 are directed to methods for the identification of test compounds that modulate chromatin remodeling of specific DNA sequences. Chromatin remodeling is an important step in activation and transcription of specific genes. The targeting of chromatin remodeling complexes to specific nucleic acid sequences (genes) in chromatin has been found to occur through the interaction of one or more subunits of a chromatin remodeling complex and a domain of a nucleic acid regulatory protein. The claimed methods are directed toward the identification of compounds that disrupt the interaction of one or more subunits of a chromatin remodeling complex and a domain of a nucleic acid regulatory protein such that the targeting of the chromatin remodeling complex to specific sequences will be altered and so will transcription of specific genes. Compounds act specifically by interfering with the association of a particular subunit of a chromatin remodeling complex and a particular domain of a nucleic acid regulatory protein. In this manner, the activation or transcription of disease associated genes could be specifically disrupted. One class of nucleic acid regulatory proteins are transcription factors. Transcription factors have been implicated in a wide range of human diseases (application page 11, lines 22 to page 12, lines 6 and page 28, lines 1-33). Test compounds identified using the claimed methods could specifically alter the activation of disease associated genes by disrupting the interaction of a transcription factor domain and a chromatin remodeling complex subunit. Compounds that would alter or modulate such interaction would be useful to treat such disease conditions. Accordingly, Applicant has formulated the inventive discovery as a method for

identifying such compounds. Because the utility of the claimed invention is asserted and fully supported by the specification, withdrawal of the rejection of the claims under 35 U.S.C. § 101 is proper and is respectfully requested.

The 35 U.S.C. § 112, first paragraph, Rejections of the Claims

The Examiner rejected claims 1-37 under 35 U.S.C. 112, first paragraph alleging that the claimed invention lacks utility. Applicants respectfully submit that cancellation of claims 1-37 and addition of new claims 38-88 overcome the Examiner's rejections.

The present claims recite methods to identify compounds that modulate chromatin remodeling in a manner that allows for the alteration of the activation of specific genes, such as disease associated genes. The methods are thus a screen or test. One of skill, based on the description provided, would know how to use such a screen or test to identify active compounds. Accordingly, Applicant respectfully requests the Examiner to withdraw rejection of the claims.

The Examiner rejected claims 1-37 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicants respectfully submit that cancellation of claims 1-37 and addition of new claims 38-88 overcome the Examiner's rejections.

Applicant disclosed that a subunit of a chromatin remodeling complex can interact with a domain of a nucleic acid regulatory protein to cause chromatin remodeling in a gene specific manner (specification page 18, lines 27-29 and page 29, lines 27-31). Applicant also described assays based on the interaction of a subunit of a chromatin remodeling complex and a domain of a nucleic acid regulatory protein (specification examples 1 and 2). Such a disclosure conveys to one of skill that an interaction between a subunit of a chromatin remodeling complex and a domain of a nucleic acid regulatory protein may be used to identify compounds that modulate chromatin remodeling in a sequence specific manner.

Accordingly, Applicant respectfully asserts that those of skill in the art would realize that Applicant was in possession of the claimed methods and the Examiner is respectfully requested

to withdraw the rejections of the claims under 35 U.S.C. § 112, first paragraph.

The Examiner rejected claims 1-37 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully submit that cancellation of claims 1-37 and addition of new claims 38-88 overcome the Examiner's rejections.

Applicant described *in vitro* assays that can be used to screen for compounds that increase or decrease interaction of a subunit of a chromatin remodeling complex and a domain of a nucleic acid regulatory protein (Examples 1, 2 and 5). In addition, Applicant described chromatin remodeling and transcription assays that can be used *in vivo* and *in vitro* to identify compounds, agents and conditions under which chromatin remodeling and transcription can be modulated (Examples 1, 3 and 5). Applicant has also provided working examples of assays wherein transcription from chromatin-assembled genes can be regulated in a factor specific manner (Examples 1 and 3). These assays demonstrate that chromatin remodeling and transcriptional activation can be used to identify compounds according to the claimed methods.

Applicant respectfully submits that the present claims are fully enabled. Therefore, reconsideration and withdrawal of the rejections of the claims under 35 U.S.C. § 112, first paragraph is proper and is respectfully requested.

The 35 U.S.C. § 112, second paragraph, Rejections of the Claims

The Examiner rejected claims 1, 2, 7, 16, 20, 28, 30, 32 and 34-37 under 35 U.S.C. § 112, second paragraph, alleging that the claims are indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicants respectfully submit that cancellation of claims 1-37 and addition of new claims 38-88 overcome the Examiner's rejections.

Specifically, the Examiner alleged that it was not clear what is encompassed by the phrase "altering remodeling of chromatin".

Applicant respectfully submits that one skilled in the art would be able to discern the meaning of the phrase “modulates chromatin remodeling” given the present disclosure. For example, Applicant provides many methods by which chromatin remodeling can be detected. For example, nucleosome structural remodeling may be detected through DNase I hypersensitive site formation (page 20, lines 7-17; page 21, line 32). Protein binding may also be used to indicate chromatin remodeling (page 29, lines 14-26). Transcription assays may further be used to detect chromatin remodeling (page 20, lines 18-33). Thus, Applicant respectfully asserts that one skilled in the art would realize that “modulates chromatin remodeling” involves comparison of at least two chromatin structures under different conditions and correlating the structures with the different conditions. Accordingly, because the meaning of the claim is discernable to one of skill in the art, the Examiner is requested to withdraw the rejections of the claims under 35 U.S.C. § 112, second paragraph.

The Examiner rejected claim 7 under 35 U.S.C. § 112, second paragraph, alleging that the claim is incomplete for omitting essential structural cooperative relationships of elements, such omission amounts to a gap between the necessary structural connections. Applicants respectfully submit that cancellation of any reference to an “endogenous artificial zinc-finger” has been eliminated from the claims and therefore renders the rejection moot.

The Examiner objected to claim 20 under M.P.E.P. § 2173.05(h), as using improper Markush group language. Applicants respectfully submit that cancellation of claim 20 renders the rejection moot.

The Examiner rejected claims 2, 16, 28, 30, 32, 34 and 35 alleging that the claims are vague and indefinite because it is not clear what the term “domain within a protein” is intended to be encompassed with regard to interaction with a subunit of a chromatin remodeling complex. Applicant respectfully submits that the phrase “domain within a protein” has been eliminated from the claims. New claims 38-88 refer to a domain of a nucleic acid regulatory protein that is described within the specification to interact with a chromatin remodeling complex (page 5, lines 6-15 and page 18, lines 8-29), for example a DNA binding domain. Accordingly, Applicant respectfully requests the Examiner to withdraw the rejections of the claims.

The Examiner rejected claim 30 under 35 U.S.C. § 112, second paragraph, alleging that

the claim is incomplete for omitting essential elements, such omission amounting to a gap between the elements. Reference to use of a compound to modulate chromatin remodeling has been removed from new claims 38-88. Therefore, Applicant respectfully requests the Examiner to withdraw the rejection of the claim.

The Examiner rejected claims 35-37 under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting structural relationships relating to methods used to alter chromatin remodeling. New claims 38-88 relate to methods to identify a test compound. Therefore, Applicant respectfully requests the Examiner to withdraw the rejections of the claims.

The 35 U.S.C. § 102 Rejection of the Claims

The Examiner rejected claim 30 under 35 U.S.C. § 102(a) alleging that the claim is anticipated by Haswell et al. (Molecular and Cellular Biology, 19:2817-2827 (1999)), and under 35 U.S.C. § 102(b) alleging that the claim is anticipated by Orphanides et al. (Cell, 92:106-116 (1998)). Applicants respectfully submit that cancellation of claim 30, which is directed to an *in vitro* system to increase or decrease transcription, renders the rejection moot. New claims 38-88 relate to methods to identify a test compound.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-371-2123) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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By

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, Washington, D.C. 20231, on this 1st day of July 2002.

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